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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,444	01/22/2002	Paul M. Guyre	DC-0172	9998

7590 07/25/2002

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,444	Applicant(s) GUYRE ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Notice to comply for sequence rule.

DETAILED ACTION

1. Claims 1-5 are pending.

2. Applicant's election with traverse of Group I, Claims 1-3 drawn to a composition comprising a baculovirus expressed recombinant Fel dI and a sFv of monoclonal antibody H22, filed 6/12/02, is acknowledged. The traversal is on the grounds that (1) in the case of Group I, II and III, the method of claims 4 and 5 are depend on the composition of Group I and are not separate and distinct, (2) a search of the literature for references to a baculovirus expressing recombinant Fel dI would inherently find references to both the compositions and its uses. This is not found persuasive because of the reasons set forth in the restriction mailed 5/20/02. Inventions of Groups II-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of diagnosing versus the method of treating that differ with their respect to their method steps and endpoint. Therefore, they are patentably distinct. Inventions of Group I and Groups II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in materially different process such as making antibody or screening assays. Therefore, they are patentably distinct. Further, a prior art search of Group I, drawn to different Class and subclass, would not encompass the inventions of Groups II and III and vice versa. It is a burden to search more than one invention. Therefore, the requirement of Group I claims 1-3 and Groups II-III is still deemed proper and is therefore made FINAL.

3. Claims 4-5 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-3, drawn to a composition comprising a baculovirus expressed recombinant Fel dI and a sFv of monoclonal antibody H22 are being acted upon in this Office Action.

5. This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Amino Acid Sequence Disclosures. SEQ ID NO is required for "$(Gly_4Ser)_3$" on page 4, line 24 of the specification. Please see enclosed Notice to comply. Applicant is reminded to amend the specification and the claims to specify SEQ ID NOS., if appropriate.

6. The drawings, filed 1/22/02, are not approved. Please see enclosed PTO 948, Notice of Draftsperson's Patent Drawing Review. Appropriate action is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a composition comprising a baculovirus expressed *any* recombinant Fel dI for diagnosing cat allergy.

The specification discloses only a composition comprising a baculovirus expression vector expressed a specific recombinant Fel dI comprising chain-1 Fel dI and chain-2 linked together in series via a flexible peptide linker $(glycine_4\ Ser)_3$ and further linked to sFv H22 (H22-FelDI ch1+Ch2 sequences) for diagnosis of cat allergy in humans. The recombinant Fel dI is purified on nickel affinity column. The rFel dI shows that IgG and IgE antibody binding is identical to natural Fel dI using IgG antibody in pooled sera from either Japanese or US cat allergic patients.

With the exception of the specific composition mentioned above for diagnosing cat allergy, there is insufficient written description about the structure associated with functions of *any* recombinant Fel dI for a composition for diagnosing cat allergy. Given the lack of a written description of *any* additional representative species of recombinant Fel dI encompassed by the

claims, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "a composition" in claims 1-3 is indefinite and ambiguous. The claim as written read on a compound and not a composition.

The recitation of "sFv of monoclonal antibody H22" in claim 3 is ambiguous and indefinite because "antibody H22" is a laboratory designation and does not indicate the specificity of said antibody.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,547,669 (Aug 1996, PTO 892).

The '669 patent teaches a composition such as a recombinant cat allergen Fel dI fusion protein comprising chains I and 2 linked together via a linker such as any non-epitope amino acid sequence (See column 10, lines 13-66, in particular). The '669 patent teaches the recombinant Fel dI is useful for treating and diagnosing sensitivity in an individual to cat allergen such as Fel dI (See column 12, lines 31-33, in particular). The recitation of "a baculovirus expressed recombinant Fel dI" has no patentable weight because a product is a product, irrespective of how it is made. Thus, the reference teachings anticipate the claimed invention.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,547,669 (Aug 1996, PTO 892) in view of US Pat No. 5,837,243 (Nov 1998; PTO 892).

The teachings of the '669 patent have been discussed supra.

The claimed invention as recited in claim 2 differs from the references only that the linker is a glycine serine linker.

The claimed invention as recited in claim 3 differs from the references only that the composition further comprising a sFv of monoclonal antibody H22.

The '243 patent teaches bispecific molecules such as cat allergen linked to monoclonal antibody H22 that is specific for Fc receptor such as FcγRI (See column 7, lines 52-67 bridging column 8, lines 1-19, in particular). The '243 patent further teaches a method of making bispecific molecules using various expression constructs such as pSVgpt and pSVhyg encoding single chain antibody H22 that is specific for humanized Fc receptor such as FcγRI (See column 18, lines 24-33, in particular). The '243 patent teaches the fusion molecules is linked together via a linker such as glycine and serine $(glycine_4\ Ser)_3$ (See Figs 39B, Fig 40A, in particular). The '243 patent teaches the antibody H22 is useful for targeting any antigen to the antigen presenting cell by binding to a surface receptor such as FcγRI on the antigen presenting cells, in turn, the antigen presenting cells can internalize antigen for processing and presentation to induce

tolerance to said antigen (See column 7, lines 57-67 bridging column 8, lines 1-2, column 8, lines 57-62, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to link chain 1 and chain 2 as taught by the '669 patent using a linker such as glycine and serine $(glycine_4 Ser)_3$ as taught by the '243 patent and further linked to a sFv monoclonal antibody H22 as taught by the '243 patent for a composition comprising a recombinant Fel dI comprising chain 1 and chain 2 expressed in a series and linked together by a glycine/serine linker and a sFv of monoclonal antibody H22. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '243 patent teaches the antibody H22 is useful for targeting any antigen to the antigen presenting cell by binding to a surface receptor such as FcγRI on the antigen presenting cells, in turn, the antigen presenting cells can internalize antigen for processing and presentation to induce tolerance to allergen (See column 7, lines 57-67 bridging column 8, lines 1-2, column 8, lines 57-62, in particular).

16. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,547,669 (Aug 1996, PTO 892) in view of Bei *et al* (J Immunological Methods 186: 245-255, Oct 1995; PTO 892).

The teachings of the '669 patent have been discussed supra. The '669 patent further teaches the recombinant Fel dI is expressed in *E. Coli* (See column 2, lines 15-25, lines 65-67 bridging column 22, lines 1-7, column 12, lines 40-43, column 18, line 23, in particular). The '669 patent teaches the recombinant Fel dI is useful for treating and diagnosing sensitivity in an individual to cat allergen such as Fel dI (See column 12, lines 31-33, in particular).

The claimed invention as recited in claim 1 differs from the reference only that the composition comprising Fel dI is expressed by a baculovirus.

Bei *et al* teach the salient features of the baculovirus expression system for making any protein included high efficiency of expression, ease of purification, time saving and cost-effective method of scaling up production of functional proteins (See page 253, column 2, last paragraph, in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the *E. Coli* expression vector as taught by the '669

patent for the baculovirus expression vector as taught by Bei *et al* for a composition comprising a baculovirus expressed recombinant Fel dI. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Bei *et al* teach the salient features of the baculovirus expression system included high efficiency of expression, ease of purification, time saving and cost-effective method of scaling up production of functional proteins (See page 253, column 2, last paragraph, in particular). The '669 patent teaches the recombinant Fel dI is useful for treating and diagnosing sensitivity in an individual to cat allergen such as Fel dI (See column 12, lines 31-33, in particular).

17. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,547,669 (Aug 1996, PTO 892) in view of Bei *et al* (J Immunological Methods 186: 245-255, Oct 1995; PTO 892) as applied to claim 1 mention above and further in view of US Pat No. 5,837,243 (Nov 1998; PTO 892).

The teachings of the '669 patent and Bei *et al* have been discussed supra.

The claimed invention as recited in claim 2 differs from the references only that the linker is a glycine serine linker.

The claimed invention as recited in claim 3 differs from the references only that the composition further comprising a sFv of monoclonal antibody H22.

The '243 patent teaches bispecific molecules such as cat allergen linked to monoclonal antibody H22 that is specific for Fc receptor such as FcγRI (See column 7, lines 52-67 bridging column 8, lines 1-19, in particular). The '243 patent further teaches a method of making bispecific molecules using various expression constructs such as pSVgpt and pSVhyg encoding single chain antibody H22 that is specific for humanized Fc receptor such as FcγRI (See column 18, lines 24-33, in particular). The '243 patent teaches the fusion molecules is linked together via a linker such as glycine and serine $(glycine_4\,Ser)_3$ (See Figs 39B, Fig 40A, in particular). The '243 patent teaches the antibody H22 is useful for targeting any antigen to the antigen presenting cell by binding to a surface receptor such as FcγRI on the antigen presenting cells, in turn, the antigen presenting cells can internalize antigen for processing and presentation to induce tolerance to said antigen (See column 7, lines 57-67 bridging column 8, lines 1-2, column 8, lines 57-62, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to link chain 1 and chain 2 as taught by the '669 patent using a linker such as glycine and serine $(glycine_4 Ser)_3$ as taught by the '243 patent and further linked to a sFv monoclonal antibody H22 as taught by the '243 patent for a composition comprising a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in a series and linked together by a glycine/serine linker and a sFv of monoclonal antibody H22. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '243 patent teaches the antibody H22 is useful for targeting any antigen to the antigen presenting cell by binding to a surface receptor such as FcγRI on the antigen presenting cells, in turn, the antigen presenting cells can internalize antigen for processing and presentation to induce tolerance to allergen (See column 7, lines 57-67 bridging column 8, lines 1-2, column 8, lines 57-62, in particular). Bei *et al* teach the salient features of the baculovirus expression system included high efficiency of expression, ease of purification, time saving and cost-effective method of scaling up production of functional proteins (See page 253, column 2, last paragraph, in particular). The '669 patent teaches the recombinant Fel dI is useful for treating and diagnosing sensitivity in an individual to cat allergen such as Fel dI (See column 12, lines 31-33, in particular).

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

20. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
July 15, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No.: 10/054,444

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: SEQ ID NO is required for "$(Gly_4Ser)_3$" on page4, line 24 of the specification.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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